UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,764	02/21/2002	Carlos R. Plata-Salaman	ORT-1575	9424

27777 7590 09/10/2003

AUDLEY A. CIAMPORCERO JR.
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	6

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/081,764	Applicant(s) Plata-Salaman et al.
	Examiner Phyllis G. Spivack	Art Unit 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-32 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

A Preliminary Amendment filed February 21, 2002, Paper No. 4, is acknowledged. Claims 1-32 are presented.

The submission of an Information Disclosure Statement, Paper No. 5, filed October 28, 2002, is indicated on the file wrapper of the present application. However, no references nor Form PTO-1449 are present in the file.

Claims 1, 11, 22, 25, 26, 28, 29 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Parenthetical subject matter renders the claims in which they appear indefinite. It is unclear whether or not claim limitations are intended.

Claims 1-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to the prevention of any neurodegenerative disorder and numerous pathologies as recited in claims 20-31. The specification provides support for cell survival rates following the administration of an enantiomer of instant Formula Ib and IIb and transient cerebral ischemia in a rat model following administration of a compound of Formula Ib.

Attention is directed to In re Wands, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to prevention or treatment of a plethora of neurodegenerative disorders.

The relative skill of those in the art is generally that of a Ph.D or M.D.

Each particular neurodegenerative disorder has its own specific characteristics and etiology. The broad recitation "preventing or treating a neurodegenerative disorder" is inclusive of many conditions that presently have no established successful therapies.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The breadth of the claims

The claims are very broad and inclusive of many disorders of diverse etiology.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to the generic terms "an enantiomer of Formula Ib or Formula IIb" in Table 1 and "an enantiomer of Formula Ib" in Table 2 without reciting what compound is actually contemplated.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which particular compound would be preferred for preventing or treating the various neurodegenerative disorders that are encompassed in the claim language. The skilled artisan would expect the interaction of a particular compound in the prevention or treatment of a particular disease state to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for each agent. The instant specification sets forth no such understanding nor any criteria for extrapolating beyond the vague data presented in Examples 1 and 2. Even for the data presented, no direction

is provided to apply the information to a specific disease or disorder. Absent reasonable *a priori* expectations of success for using a particular chemotherapeutic agent to treat any particular neurodegenerative disorder, one skilled in the neurology art would have to test extensively many compounds to discover which particular disorder responds to that particular compound. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by et al., U.S. Patent 5,854,283.

Choi teaches the administration of compounds of instant Formulas I and II to treat disorders of the central nervous system. See column 3. In addition to exhibiting neuroprotective properties, convulsions, epilepsy, stroke and muscle spasm, which characterize neurodegenerative disorders, are specifically highlighted as therapeutic endpoints. The disclosure encompasses pure enantiomeric forms and enantiomeric mixtures wherein one of the enantiomers predominates to the extent of about 90% or greater, preferably, about 98% or greater.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

September 7, 2003

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER